

<b>Notice of Allowability</b>	Application No.	Applicant(s)
	10/633,325	SUMMERS ET AL.
	Examiner	Art Unit
	Raymond J. Henley III	1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS. This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1.  This communication is responsive to the amendment filed December 16, 2005.
2.  The allowed claim(s) is/are 1,2 and 5-11.
3.  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a)  All
  - b)  Some\*
  - c)  None
  1.  Certified copies of the priority documents have been received.
  2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3.  Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4.  A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5.  CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
  - (a)  including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
    - 1)  hereto or 2)  to Paper No./Mail Date \_\_\_\_\_.
  - (b)  including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6.  DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

The Drawings filed August 2, 2003 are acceptable

**Attachment(s)**

1.  Notice of References Cited (PTO-892)
2.  Notice of Draftperson's Patent Drawing Review (PTO-948)
3.  Information Disclosure Statements (PTO-1449 or PTO/SB/08),  
Paper No./Mail Date \_\_\_\_\_
4.  Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5.  Notice of Informal Patent Application (PTO-152)
6.  Interview Summary (PTO-413),  
Paper No./Mail Date 01242005
7.  Examiner's Amendment/Comment
8.  Examiner's Statement of Reasons for Allowance
9.  Other \_\_\_\_\_.

  
**RAYMOND HENLEY III**  
**PRIMARY EXAMINER**  
*Aut 16/04*

### **EXAMINER'S AMENDMENT/COMMENTS**

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Nick A. Nichols on January 24, 2006.

The application has been amended as follows:

**In the Claims:**

**In claim 2**, "from stem cells" has been changed to ---from endogenous stem cells---;

Claim 3 has been canceled;

**In Claim 5**, "muscle cells are recruited to said specific muscle mass in response to exercise of said specific muscle mass" has been changed to ---said muscle cells are recruited to said specific muscle mass in response to said exercise of said specific muscle mass---;

**In claim 6**, "exercise stimulate the muscle cells" has been changed to ----said exercise stimulates the muscle cells---;

**In claim 7**, "the step of using nicotine or a nAChR agonist" has been changed to ---the step of using administering nicotine or a nAChR agonist---;

**In claim 9**, "The method of claim 8" has been changed to ---The method of claim 8 2---;

**In claim 10**, "The method of claim 5 wherein exercise" has been changed to --- The method of claim 5 wherein said exercise---.

*Comments*

Applicants' amendment filed December 16, 2005 has been received and entered into the application. Accordingly, the specification at pages 1 and 3 and claims 1, 5, 6, 8-11 have been amended and claim 4 has been canceled.

It should be noted that in the above Examiner's amendment, claim 1 was not amended with respect to a type of stem cell because the claim does not recite that the muscle cells are differentiated from any type of stem cells. Also, it would be improper to conclude that claim 1 could include muscle cells differentiated from exogenous stem cells because in the previous Office action, it was set forth that such is not enabled and the standard of enablement with respect to inoperative embodiments is whether a person of ordinary skill in the art could determine which embodiments were operative with no more effort than is ordinarily required in the art.<sup>1</sup> In this regard, the C.C.P.A. has held that claims do not function to specifically exclude possible inoperative species.<sup>2</sup> From a fair reading of the record, including the specification and the previous Office action, such would have allowed a person of ordinary skill in the art to determine for which muscle cells the claimed method would be useful.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J. Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

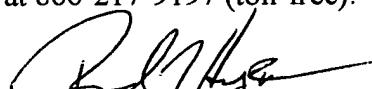
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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<sup>1</sup> M.P.E.P. 2164.08(b)

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Raymond J Henley III  
Primary Examiner  
Art Unit 1614

January 24, 2005

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<sup>2</sup> In re Dinh-Nguyen, 492 F.2d, 856, 859 (C.C.P.A. 1974).